DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 28 1994

Re: Paxil
Docket No. 93E-0146

#9

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application for U.S. Patent No. 4,721,723 filed by Beecham Group p.l.c. under 35 U.S.C. § 156. The patent claims the human drug product Paxil (paroxetine hydrochloride), NDA 20-031.

In the August 23, 1993 issue of the Federal Register (58 Fed. Reg. 44,522), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before February 21, 1994, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Edward T. Lentz
Corporate Patents U.S. - UW2220
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